Recast of the Medical Devices Directives

Patient Safety Working Group Meeting

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Recast of Medical Devices Directives

- Simplification exercise (MDD and AIMD and Blood Directives)
- Number of drivers to consider a more fundamental exercise

Recast of Medical Devices Directives

- Simplification exercise (MDD and AIMD and Blood Directives)
- Coherence and uniform application of the key elements to the framework are Market Surveillance, Vigilance, Notified Bodies, Clinical Evaluation and Transparency
- New and emerging technologies
- Revision of the New Approach
- National variation (e.g. transposition, definition of a medical device, national registration procedures, classification and interpretation of guidance)
- The Global Harmonisation Task Force for Medical Devices, GHTF

Recast of Medical Devices Directives

- Public Consultation

  http://ec.europa.eu/enterprise/medical_devices/index_en.htm

Recast of Medical Devices Directives

Elements of Public Consultation:

- Scope
- Revision of New Approach
- Evaluation procedures
- Vigilance
- Market Surveillance
- Borderline
- The Global Harmonisation Task Force for Medical Devices, GHTF
- Imports, Exports and counterfeiting
- Simplification

Recast of Medical Devices Directives

- Social and Economic impacts on ideas and proposals to strengthen the system
- Open until July 2nd 2008
- Many options interlinked
- Open – other proposals on solutions are very welcome
- Please give figures in your response positive and negative (Euros per year, man-days per month etc.)

Thank you for your attention

And Please contribute to the Public Consultation

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